AR201-13875

Ciba Specialty Chemicals Corporation
540 White Plains Road
Tarrytown, New York USA 10591

Ciba

US Environmental Protection Agency
HPV Challenge
Attn: Oscar Hernandez, Director
Risk Assessment Division
P.O. Box 1473
Marrifield, VA 22116

June 24, 2002

Subject: EPA Comments on HPV Challenge Test Plan for 2-Hydroxy-4-n-Octoxybenzophenone

Dear Dr. Hernandez:

Cytec Industries, Inc. and Ciba Specialty Chemicals Corporation submitted a test plan and robust summaries to the EPA for 2-hydroxy-4-n-octoxybenzophenone (CAS No. 1843-05-6) dated October 10, 2001. EPA posted comments on the test plan on April 9, 2002.

EPA generally agreed with the submitted test plan. The following additional data or testing was requested by the Agency. The comments of the sponsors, Ciba and Cytec, follow each Agency comment.

1. EPA: *Physicochemical and Environmental Fate Data.* "EPA agrees with the Test Plan and Robust Summaries for these endpoints. The submitters need to clarify the method used for the biodegradation test."

   Sponsor response: A revised robust summary on the biodegradation testing is included with this letter.

2. EPA: *Health Endpoints.* "The submitters plan to conduct no further testing for acute toxicity, repeated-dose toxicity, and genetic toxicity is acceptable. EPA recommends that a reproductive/developmental toxicity test (OECD 421) be performed. The available study used a dose level that was significantly lower than the guideline-recommended limit dose."

   Sponsor response: The submitted reproduction study evaluated reproductive and developmental toxicity in rats over 4 generations. Treated rats received a diet containing 6000 ppm of 2-hydroxy-4-n-octoxybenzophenone which resulted in exposures of approximately 524 mg/kg/day for males and 614 mg/kg/day for females. There were no adverse effects noted on reproductive performance or development of offspring. The use of 2-hydroxy-4-n-octoxybenzo-phenone as a UV absorber / light stabilizer in various polymers will result in minimal human exposure and in view of its apparent low potential to act as a reproductive toxin, as

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demonstrated by existing data, the sponsors do not believe that further testing is warranted.

3. EPA:. Ecotoxicity, comment 1: "Because this chemical has a high Log Kow, a chronic daphnia test is recommended."

   Sponsor response (1): Daphnia Chronic testing: An acute toxicity test with Daphnia was conducted following OECD guidelines. This showed that the compound is only slightly toxic to aquatic invertebrates with an EC50 of 52 mg/L. The principal use of 2-hydroxy-4-n-octoxybenzo-phenone is as a UV absorber / light stabilizer in polymers which is not expected to result in significant environmental exposure. In view of its demonstrated low toxicity and low potential for environmental exposure, the sponsors believe that the available test data are adequate for hazard and risk assessment purposes and that no further testing should be conducted at this time.

   EPA:. Ecotoxicity, comment 2: "The submitters should also conduct an acute test in algae because the submitted test was inadequate due the use of a dispersant."

   Sponsor response (2): Acute Algae testing: A toxicity test with green algae was submitted with test exposures ranging from 1.23 to 100 mg/L. The study results showed that the compound was not toxic to algae with an EC50 value greater than the highest test exposure of 100 mg/L. Because 2-hydroxy-4-n-octoxybenzophenone has very low water solubility, the experimenters sought to enhance dispersion of the test material in the assay water by dissolving the compound in a small amount of solvent (NMP and Tween 80). The sponsors believe that, contrary to Agency opinion, this procedure increased exposure of algae to the test substance and that the test therefore maximized potential toxicity. We also note that no toxic response was observed at the limit dose of 100 mg/L. In the opinion of the sponsors, repeating the study would not provide useful information.

Richard Balcomb

For joint sponsors:

Ciba Specialty Chemicals Corporation
540 White Plains Road
Tarrytown, New York 10591

Cytec Industries, Inc.
Five Garret Mountain Plaza
West Paterson, NJ 07424

Enclosures: 1) Robust Summary for Biodegradation Study
2) Computer Disk with electronic copies of letter and robust summary